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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,869

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Ask Puschl

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08/26/2008

LUNDBECK RESEARCH USA, INC.

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

08/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,869	Applicant(s) PUSCHL ET AL.	
	Examiner Taofiq A. Solola	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14, 16 and 18-40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14, 16, 18-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-14, 16, 18-40 are pending in this application.

Claims 15, 17, are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 16, 18-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al., J. Med. Chem. (1979), Vol. 22(11), pp. 1347-1354, in view of Silverman, The Org. Chem. of Drug Design and Drug Action, (1992) San Diego, Academic Press, Pp. 19.

Applicant claims compounds of formula I, their composition and method of use for treating affective disorder.

Determination of the scope and content of the prior art (MPEP 2141.01)

Martin et al., teach similar compounds their composition and method of use for treating affective disorder. See the abstract, and the examples in Table III, page 1350.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Martin et al., is that in compounds of the prior art, applicant replaced -CH₂- with -S-. Some of the compounds of Martin et al., are 3⁰ amines instead of 2⁰ amines in the instant and some are position isomers of the instant compounds.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, Silverman teaches that replacement of -CH₂- with -S- in a compound is expected to produce compounds having similar biological activity (bioisosterism). See page 19,

bivalent atoms and groups. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir. 1986).

Also, 2° and 3° amines are obvious variants. *Ex parte Bluestone*, 135 USPQ 199 (1961). A novel and useful compound, which is an isomer of a compound of prior art, is prima facie obvious. *In re Norris*, 84 USPQ 458 (1950).

Therefore, the instant invention is prima facie obvious from the teachings of Martin et al., and Silverman. One of ordinary skill in the art would have known to replace -CH₂- with -S- in the compounds of Martin et al., at the time the instant invention was made. The motivation is from knowing that -CH₂- and -S- are bioisosteres equivalents.

Alternatively, given the teachings of the prior arts, it would have been obvious to try replacement of -CH₂- with -S- in the compounds of Martin et al., at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, applicant has done nothing more than substitutes known bioisosteres equivalents in prior arts' compounds. However, such substitution is obvious from the prior arts and knowledge of bioisosteres equivalents. "When a patent claims a structure already known in

the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *United States v. Adams*, 383 U.S. 49, 50-51 (1966). Cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR, supra*.

Response to Argument

Applicant's arguments filed 6/3/08 have been fully considered but they are not persuasive. Applicant contends none of the prior arts provides motivation and/suggestion to modify the compounds of the prior art. This argument is foreclosed by the recent decision in *KSR Int. Co. v. Teleflex Inc.*, 127 S.Ct, at 1741, 82 USPQ2d 1385 at 1396 (2007).

The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The instant rejection is based on knowledge generally available in the art: that -CH₂- and -S- are bioisosteres equivalents and isomers have similar biological activities.

Applicant may overcome the obviousness rejection by a showing of unexpected results through side-by-side study.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

August 24, 2008